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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/614,483	07/10/2000	Jennie P. Mather	145072000110	1943

25226 7590 01/16/2003
MORRISON & FOERSTER LLP
755 PAGE MILL RD
PALO ALTO, CA 94304-1018

EXAMINER

EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 01/16/2003

#24

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/614,483

Applicant(s)

Mather et al.

Examiner

G.R. Ewoldt

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Dec 16, 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☒ Applicant's reply has overcome the following rejection(s):
112/1, enablement, of Claims 10 and 40

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See attachment

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: none

Claim(s) objected to: none

Claim(s) rejected: 1-6, 8-13, 16-21, 23, 31-36, 38-42, 45-47, and 59-67

Claim(s) withdrawn from consideration: 7, 14, 15, 22, 37, 43, and 44

8. ☐ The proposed drawing correction filed on _____ is a) ☒ approved or b) ☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

10. ☐ Other: _____

Patrick J. Nolan
PATRICK J. NOLAN, PH.D.
PRIMARY EXAMINER
1/15/03



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09/614483

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER

DATE MAILED:

The decision on the petition filed in the above entitled application is as follows:

☐ Delay in Prosecution Held Unavoidable (35 U.S.C. 133),
Petition Granted _____

☐ Delayed Payment of Issue Fee Accepted (35 U.S.C. 151),
Petition Granted _____

☒ Petition Granted The petition under 37 CFR 1.84(a)(2) to accept
color drawings filed on 12/16/02
is hereby granted.

☐ Petition Denied _____

☐ Petition Dismissed _____

By direction of the Deputy
Assistant Commissioner for Patents

Christina Chan
CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

DETAILED ACTION

1. Applicant's petition to accept color drawings has been granted.

2. In view of Applicant's amendment and response, filed 12/15/02, the previous rejections of Claims 10 and 40 under the first paragraph of 35 U.S.C. 112, in regards to a lack of enablement, have been withdrawn.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-6, 8-13, 16-21, 23, 31-36, 38-42, and 45-47 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,932,704, in view of U.S. Patent 5,714,385, for the reasons of record as set forth in Papers No. 14 and 20, mailed 1/15/02 and 8/30/02, respectively.

Applicant's arguments, filed 12/16/02, have been fully considered but they are not persuasive. Applicant reiterates the previous arguments by again arguing against the references individually. Accordingly, the rejections are maintained for the reasons of record.

Several specific points must be addressed however, such as Applicant's assertion that "the '704 patent does not teach or suggest a method of producing or generating a population of monoclonal antibodies, as well as a method of producing or generating a plurality of monoclonal antibodies using viable whole cells and antigens in a "native configuration", as stated by the Examiner. Instead, the '704 patent only teaches a method of producing or generating antibodies capable binding to a subunit of human GM-CSF receptor using cells expressing high levels of this known specific receptor," must be addressed. It is the Examiner's position that the polyclonal antibodies of the reference can be considered to be "a population of monoclonal antibodies" as set forth in the instant claims. Further, the GM-CSF receptor can be considered a "cell surface antigen representative of a specific cell type, " e.g., a monocyte.

Regarding Applicant's argument that "To establish a *prima facie* case of obviousness, there must be some suggestion, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings," said motivation has been set forth previously in the action mailed 1/15/02.

Regarding Applicant's argument that "There is nothing in this disclosure [the '704 patent] which even suggests generating a population of antibodies which bind to cell surface antigens representative of a specific cell type. Only a single antigen is disclosed." Applicant is advised that even a single antigen would elicit an immune response that would comprise many different antibodies, i.e., "a population of monoclonal antibodies".

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-6, 8-13, 16-21, 23, 31-36, 38-42, 45-47, and 59-67 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed, for the reasons of record as set forth in Paper No. 20, mailed 8/30/02, respectively.

Applicant's arguments, filed 12/16/02, have been fully considered but they are not persuasive. Applicant argues that Example 2 provides adequate written support for the recitation of "repeatedly" and "repeatedly without adjuvant". Applicant admits that the term "repeatedly" is not disclosed in the specification. The Examiner maintains the position that the single disclosure is insufficient to describe the method as is now broadly claimed.

Applicant argues that the disclosure of a method that "maximizes the preservation of intact antigens" supports the instant claims that recite a method to "preserve the native configuration of the surface antigens on the cells". The Examiner disagrees. Applicant is advised that, as Applicant considers the phrases to be identical, Applicant could obviate

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the rejection by amending the claims to recite the terminology disclosed in the specification.

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center at (703) 305-3014.

G.R. Ewoldt, Ph.D.
Patent Examiner
Technology Center 1600
January 14, 2003

Patrick J. Nolan, Ph.D.
Primary Examiner
Technology Center 1600